APPLICATION FOR A NOMENCLATURE CHANGE IN THE TABLE TO CLAUSE 17 of 'STANDARD 1.3.3 – PROCESSING AIDS' in the AUSTRALIAN NEW ZEALAND FOOD STANDARDS CODE

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EXECUTIVE SUMMARY

In the current version of the Table to clause 17 of 'Standard 1.3.3 – Processing Aids' in the Australian New Zealand Food Standards Code, the enzyme Carboxyl proteinase (3.4.23.6) from sources: *Aspergillus melleus*, *Aspergillus niger*, *Aspergillus oryzae* and *Rhizomucor miehei* is listed as one of the permitted enzymes. A nomenclature change by the international Union of Biochemistry and Molecular Biology (IUBMB) has superseded 3.4.23.6 and replaced it with twelve different enzyme numbers, related to their sources. These are: EC 3.4.23.18-28, 3.4.23.30. The purpose of this application is to request an amendment to the Table to clause 17 of Standard 1.3.3 to reflect this nomenclature change without providing broader permissions than the status quo position.

A review of the twelve enzymes that have replaced 3.4.23.6 shows that only three of the twelve can be sourced from any of the four microorganisms linked to the current enzyme permission. These three are: Aspergillopepsin I (3.4.23.18), Aspergillopepsin II (3.4.23.19) and Mucorpepsin (3.4.23.23). Since Mucorpepsin (3.4.23.23) is already listed in a separate entry of the Table to clause 17 of 'Standard 1.3.3 – Processing Aids', it can be discounted from this application. This leaves Aspergillopepsin I (3.4.23.18) from *Aspergillus niger* or *Aspergillus oryzae* and Aspergillopepsin II from *Aspergillus niger* (3.4.23.19) as the only two enzymes from the outdated classification 3.4.23.6 that can be sourced from the permitted microorganisms and are therefore relevant to this application.

The proposed nomenclature change is therefore to replace the current outdated entry:

Enzyme	Source
Carboxyl proteinase EC 3.4.23.6	*Aspergillus melleus* *Aspergillus niger* *Aspergillus oryzae* *Rhizomucor miehei*

With:

Enzyme	Source
Aspergillopepsin I (3.4.23.18)	*Aspergillus melleus* *Aspergillus niger* *Aspergillus oryzae* *Rhizomucor miehei*
Aspergillopepsin II (3.4.23.19)	*Aspergillus niger*

After conducting several years of trials, the Australian wine industry wishes to use a mixture of Aspergillopepsin I (3.4.23.18) and Aspergillopepsin II (3.4.23.19) as a processing aid in wine production. The enzyme mixture will be used to remove haze-forming proteins from grape juice, avoiding the need for later protein stabilisation of wine using bentonite clay. Due to the current entry for carboxyl proteinase in the table to clause 17 of Standard 1.3.3 having been superseded, the Australian wine industry does not currently have regulatory certainty regarding the use of these enzymes.

GENERAL REQUIREMENTS

3.1.2 Applicant details

(a) [redacted]
(b) The Australian Wine Research Institute Ltd
(c) Postal Address: PO Box 197, Glen Osmond, SA 5064
Physical Address: Hartley Grove, cnr Paratoo Rd, Urrbrae SA 5064
(d) (08) 8313 6600
(e) [redacted]
(f) Wine Research Organisation
(g)Other organisations associated with the application: None

3.1.3 Purpose of the application

The purpose of the application is to request that an update be made to the Table to clause 17 of Standard 1.3.3 to reflect a nomenclature change made by the International Union of Biochemistry and Molecular Biology (IUMB). Specifically the application requests replacement of the current entry:

Enzyme	Source
Carboxyl proteinase EC 3.4.23.6	*Aspergillus melleus* *Aspergillus niger* *Aspergillus oryzae* *Rhizomucor miehei*

With:

Enzyme	Source
Aspergillopepsin I (3.4.23.18)	*Aspergillus melleus* *Aspergillus niger* *Aspergillus oryzae* *Rhizomucor miehei*
Aspergillopepsin II (3.4.23.19)	*Aspergillus niger*

3.1.4 Justification for the application

Need for proposed change: The current enzyme nomenclature for carboxyl proteinase (EC 3.4.23.6) currently in the Australian New Zealand Food Standards Code is out of date, and has been replaced by the IUBMB with 12 new entries: EC 3.4.23.18-28 and EC 3.4.23.30. The Australian wine industry wishes to use two of these enzymes (EC 3.4.23.18 and 3.4.23.19) to treat wine, but does not currently have regulatory

certainty because they are not specifically listed in the, Code, and because the enzyme number listed in the Code is no longer current.

It is noted that nine of the remaining new enzymes (EC 3.4.23.20-22, 3.4.23.24-28, 3.4.23.30) are not sourced from the approved microorganisms associated with the current permission for carboxyl proteinase. They are therefore not relevant to be listed. The one additional enzyme Mucorpepsin (EC3.4.23.23) which can be sourced from an approved organism is already listed as a separate entry in the Table to clause 17 of Standard 1.3.3.

Advantages over status quo: By updating the enzyme entry to reflect the IUMB's current nomenclature, confusion for enzyme users will be removed and they will have regulatory certainty that they do not currently have. The Australian wine industry will benefit from being able to use these enzymes as an alternative treatment to remove haze-forming proteins, with both economic and environmental benefits.

A Regulatory impact information

- Costs and benefits
    - This change would have no impact on consumers, as this is purely a nomenclature change
    - Ability to use EC 3.4.23.18 and 3.4.23.19 in the wine industry as a result of this nomenclature change will provide both economic and environmental benefits over the current standard treatment to remove haze-forming proteins.
    - No additional regulatory costs are foreseen from this nomenclature change
- Impact on international trade
    - The total impact on international trade of the use of EC 3.4.23.18 and 3.4.23.19 as processing aids in the wine industry will be relatively small, as the mass of enzyme preparation required is only a few grams per 1000L of juice or wine.
    - The use of EC 3.4.23.18 and 3.4.23.19 as processing aids may result in a small reduction in trade volumes of bentonite clay if there was widespread wine industry uptake of the alternative enzyme treatment.

3.1.5 Information to support the application

There are no public health and safety issues related to the change of nomenclature requested in this application. Similarly, no consumer choice issues are raised. Updated safety information is provided in section C.

This application is supported by the Winemakers Federation of Australia, representing the Australian wine industry.

3.1.6 Assessment procedure

We consider that this application should be assessed via a General Procedure. Although the basis of this application is a nomenclature change and the change seeks to update an entry for an already approved Processing Aid, it would be prudent to undertake a wider consultative approach to capture any relevant concerns from all stakeholders.

3.1.7 Confidential commercial information

No confidential commercial information is incorporated in this dossier.

3.1.8 Exclusive capturable commercial benefit (ECCB)

This application is not expected to confer an ECCB.

3.1.9 International and other Standards

International Standards

- Protease from *Aspergillus oryzae,* var. is included in the LIST OF CODEX SPECIFICATIONS FOR FOOD ADDITIVES (CAC/MISC 6-2012).

Other National Standards or Regulations

- Proteases from *Aspergillus niger* are approved by the FDA for treatment of wine and juice to reduce or remove heat labile proteins (Code of Federal Regulations, Title 27, Section 24.246 – Materials authorized for the treatment of wine and juice).
- Proteases from *Aspergillus niger* have been notified as Generally Recognised as Safe (GRN No. 89 – US FDA GRAS Notice Inventory)
- Proteases from *Aspergillus oryzae* have been notified as Generally Recognised as Safe (GRN No. 90 – US FDA GRAS Notice Inventory)
- Protease enzymes from *Aspergillus niger* and *Aspergillus oryzae* are approved by the Food and Drug Regulations of Canada for use in a range of food and beverages including Beer, Cheese, Bread, Meat cuts and Plant-based beverages – Food and Drug Regulations (C.R.C., c. 870), Section B.16.100, Table V

3.1.10 Statutory declaration

This application is accompanied by a Statutory Declaration.

3.1.11 Checklist

A checklist for General Requirements and for Applications Relevant To Section 3.3.2 – Processing Aids can be found at the end of this document.

II PROCESSING AIDS

A. Technical information on the processing aid

1. Information on the type of processing aid

The type of processing aid being discussed in this application is category (o) – Enzymes of microbial origin.

2. Information on the identity of the processing aid

The enzymes being referred to in this application are: EC 3.4.23.19 Aspergillopepsin II, a nonpepsin-type acid proteinase from *Aspergillus niger* and EC 3.4.23.18 Aspergillopepsin I, a typical pepsin-type aspartic proteinase from *Aspergillus niger* or *Aspergillus oryzae*. These two enzymes were formerly incorporated under EC 3.4.23.6 – Carboxyl proteinase.

3. Information on the chemical and physical properties of the processing aid

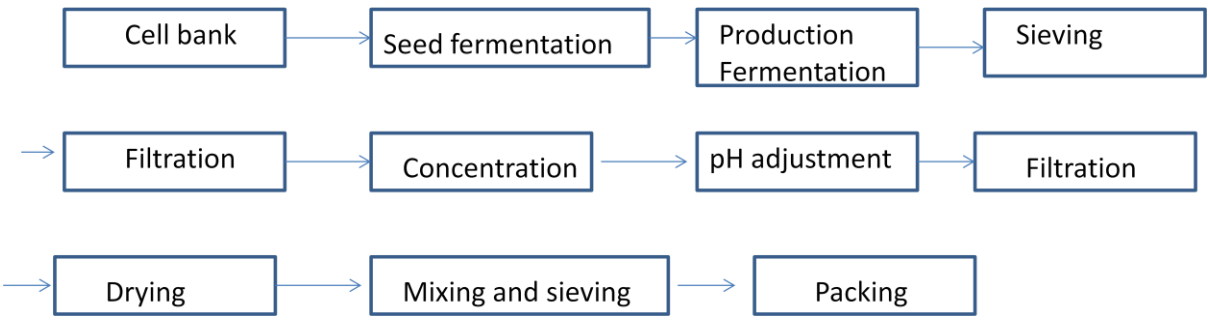
A concentrated protease powder produced from non-GMO fungi containing usually not less than 950,000 units/g of Protease activity at pH 2.6. One unit is defined as the activity that generates 1 microgram of tyrosine in 10 minutes at 37.0 +/- 0.5^{o}C in 1% casein solution in the presence of 1% enzyme.

Aspergillopepsin I is a pepsin-type aspartic proteinase while Aspergillopepsin II is a non-pepsin-type acid proteinase. The two enzymes are present as the major and minor components, respectively, of the commercial enzyme powder. The mixture of Aspergillopepsin I and II catalyses the hydrolysis of proteins with broad specificity, is very active at acidic pH (2-4) and high temperatures (50-80ºC), features that confer the ability to work efficiently during flash pasteurisation of juice, during which they can easily hydrolyse the peptide bonds of the grape proteins when they are in their heat unfolded status.

The enzyme(s) will be dissolved in grape juice or wine, so will not be present in food in a particulate form.

4. Manufacturing process

The protease mixture is manufactured according to the following flow chart:



5. Specification for identity and purity
   The preparation contains 92-96% crude protease and 4 – 8% Calcium lactate.

   The final enzyme preparations are analysed for the following parameters:

Parameter	**Specification**
Colour	Pale yellowish brown to yellowish brown
Form	Powder
Appearance	Contamination or visible foreign matter is not observed
Protease activity (pH 2.6)	Not less than 950,000 units/g
Loss on drying	Not more than 10.0%
pH	3.5-5.5
Arsenic	Not more than 3 ppm
Lead	Not more than 5 ppm
Heavy metals	Not more than 40 ppm
Coliforms	Not more than 30 cfu/g
Salmonella	Not detected in 25 g
E. coli	Not detected in 25 g
Total viable count	Not more than 5 x 10^4 cfu/g
Antibiotic activity	Not detected
Mycotoxins (Aflatoxin B1, ochratoxin A, sterigmatocystin, zearalenone, nivalenol, deoxynivalenol)	Not detected

6. Analytical method for detection
   Not applicable – because this application is for an enzymatic processing aid.

C. Information related to the safety of an enzyme processing aid

1. General information on the use of the enzyme as a food processing aid in other countries

- Proteases from *Aspergillus niger* are approved by the FDA for treatment of wine and juice to reduce or remove heat labile proteins (Code of Federal Regulations, Title 27, Section 24.246 – Materials authorized for the treatment of wine and juice).
- Proteases from *Aspergillus niger* have been notified as Generally Recognised as Safe (GRN No. 89 – US FDA GRAS Notice Inventory)
- Proteases from *Aspergillus oryzae* have been notified as Generally Recognised as Safe (GRN No. 90 – US FDA GRAS Notice Inventory)
- Protease enzymes from *Aspergillus niger* and *Aspergillus oryzae* are approved by the Food and Drug Regulations of Canada for use in a range of food and beverages including Beer, Cheese, Bread, Meat cuts and Plant-based beverages – Food and Drug Regulations (C.R.C., c. 870), Section B.16.100, Table V

2. Information on the potential toxicity of the enzyme processing aid

- Enzymes produced by *Aspergillus niger* and *Aspergillus oryzae* have been used in food production for several decades. In the USA, proteases from *Aspergillus niger* and *Aspergillus oryzae* have been notified as Generally Recognised as Safe (GRN numbers 89 and 90). The Australian and New Zealand Food standards code contains numerous enzymes produced by *Aspergillus niger* and *Aspergiullus oryzae* in the list of permitted additives. These include: α–Amylase, Asparaginase, β-Galactosidase, β-Glucanase, Glucoamylase and α-Glucosidase.

3. Information on the potential allergenicity of the enzyme processing aid

There is significant evidence in the literature that the ingestion of food enzymes is not of concern with respect to food allergy, even in individuals with inhalation allergies to the same enzymes (Pariza & Foster, 1983, J Food Prot, 46: 453-468; Bindslev-Jensen et al, 2006. Food Chem. Toxicol. 44: 1909-1915; GRAS Notice 333, 2010, http://www.accessdata.fda.gov/scripts/fcn/fcnDetailNavigation.cfm?rpt=grasListing&id=333)

The protease mixture is produced from a fermentation medium that includes two components that are currently listed as allergens in Section *Mandatory declarations of certain substances in food* in Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations, namely:

- Soybean
- Gluten

The Table below summarises those allergenic substances used in manufacture of the protease mixture and those that are manufactured on the same production line. The manufacturer has indicated that it is considered very unlikely that any of these allergenic materials would be present in the final product (protease mixture).

Gluten
Egg
Milk
Lactose
Peanuts
Shellfish
Fish
Soybean
Nuts
Wheat
Buckwheat

4. Safety assessment reports prepared by international agencies or other national government agencies if available.
   Not found.

D.

1. Information on the source microorganism
   No changes are being requested to the permitted source organisms *Aspergillus niger* and *Aspergiullus oryzae* already listed in the Food Standards Code.

2. Information on the pathogenicity and toxicity of the source microorganism

   Aspergillus niger is known to naturally occur in foods. The fungus is commonly present in products like rice, seeds, nuts, olives and dried fruits. For several decades, *Aspergillus niger* has been safely used in the commercial production of organic acids and food enzymes. Schuster et al. published a review of the safety of Aspergillus niger in 2002 which concluded that it is a safe production organism, so long as ochratoxin A production is excluded.

Aspergillus oryzae has been used for centuries in the production of many different Asian foods such as soy sauce, sake and miso. It is also used to produce livestock probiotic feed supplements. Enzymes from *Aspergillus oryzae* were among the first to be isolated and commercialised nearly 100 years ago.

3. Information on the genetic stability of the source organism

Not applicable.

E. Additional information related to the safety of an enzyme processing aid derived from a genetically modified microorganism

This section is not relevant to this application as it does not concern processing aids derived from genetically modified microorganisms.

F. Information related to the dietary exposure to the processing aid

1. A list of foods or food groups likely to contain the processing aid or its metabolites

Wine.

2. The levels of residues of the processing aid or its metabolites for each food or food group (Chemical identity of the residue must be stated)

No remains of the source organism will remain in the final wine. Some residual protease activity is to be expected in wines made from juice treated with the enzymes – however this is a relatively small contribution to the background protease levels naturally present in wine.

3. For foods or food groups not currently listed in the most recent Australian or NZ National Nutrition Surveys, information on the likely level of consumption

Wine is listed in the most recent Australian National Nutrition survey.

4. Percentage of the food group in which the processing aid is likely to be found or the percentage of the market likely to use the processing aid.

It is difficult to predict the uptake of the new enzymatic processing treatment. Economic analysis demonstrates that the new treatment is substantially cheaper than conventional 'batch' bentonite treatment, which is used on an estimated 75% to 80% of wine volume to which the new treatment could potentially be applied. However, a change to the new treatment requires capital expenditure on behalf of wine producers, which is likely to slow down its uptake. However, in the medium to longer term (ten

year horizon), the new treatment could become the standard treatment used throughout the wine industry.

5. Information relating to the levels of residues in foods in other countries

   Not applicable.

6. For food where consumption has changed in recent years, information on likely current food consumption.

   Not applicable.

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STATUTORY DECLARATION – AUSTRALIA

[redacted]

I, [***Name, address and occupation of person making the declaration***] Manager/Winemaker make the following declaration under the Statutory Declarations Act 1959:

1. the information provided in this application fully sets out the matters required

2. the information provided in this application is true to the best of my knowledge and belief

3. no information has been withheld that might prejudice this application, to the best of my knowledge and belief

I understand that a person who intentionally makes a false statement in a statutory declaration is guilty of an offence under section 11 of the Statutory Declarations Act 1959, and I believe that the statements in this declaration are true in every particular.

[redacted]

[***Signa ng the declaration***]

Urrbrae 16 September 2013

Declared at [***place***] on [***day***] of [***month***] [***year***]

Before me,

[redacted]

[***Signature of person before whom the declaration is made***]*

[Full name, qualification and address of person before whom the declaration is made (in printed letters)]

[redacted]

Solicitor

A Commissioner for taking affidavits in the Supreme Court of South Australia

[redacted]

* A statutory declaration must be made before a prescribed person under the Statutory Declarations Act 1959, available online at http://www.frli.gov.au/ComLaw/Legislation/ActCompilation1.nsf/current/bytitle/7E3AE20F832 9B422CA256F71004DB642?OpenDocument&mostrecent=1.

CHECKLIST FOR GENERAL REQUIREMENTS

This Checklist will assist you in determining if you have met the information requirements as detailed in Section 3.1 – General Requirements. All applications must include this Checklist.

General requirements (3.1)

√	3.1.1 Form of application √ *Application, abstracts and other key documents in English* √ *Executive Summary (separated from main application electronically and in hard copy)* √ *Relevant sections of Part 3 clearly identified* √ *Pages sequentially numbered* √ *Electronic copy (searchable)* √ *1 hard copy* √ *Electronic and hard copy identical* √ *Hard copy capable of being laid flat* √ *All references provided (in electronic and hard copy)*	√	3.1.6 Assessment procedure √ *General* ☐ *Major* ☐ *Minor* ☐ *High level health claim variation*
		N/A	3.1.7 Confidential Commercial Information ☐ *Confidential material separated in both electronic and hard copy* ☐ *Formal request including reasons* ☐ *Non-confidential summary provided*
√	3.1.2 Applicant details	N/A	3.1.8 Exclusive Capturable Commercial Benefit √ *Justification provided*
√	3.1.3 Purpose of the application	√	3.1.9 International and other national standards √ *International standards* √ *Other national standards*
√	3.1.4 Justification for the application √ *Regulatory impact information* √ *Impact on international trade*	√	3.1.10 Statutory Declaration
√	3.1.5 Information to support the application √ *Data requirements*	√	3.1.11 Checklist/s provided with application √ *3.1 Checklist* √ *Any other relevant checklists for Parts 3.2-3.7*

CHECKLIST FOR APPLICATIONS RELEVANT TO SECTION 3.3.2 – PROCESSING AIDS

Processing Aids (3.3.2)			
√	A.1 Type of processing aid	√	C.3. Allergenicity information of enzyme (enzyme only)
√	A.2 Identification information	N/A	C.4. Overseas safety Assessment Reports
√	A.3 Chemical and physical properties	√	D.1 Information on source organism (enzyme from microorganism only)
√	A.4 Manufacturing process	√	D.2 Pathogenicity and toxicity of source microorganism (enzyme from microorganism only)
√	A.5 Specification information	N/A	D.3 Genetic stability of source organism (enzyme from microorganism only)
N/A	A.6 Analytical method for detection	N/A	E.1 Nature of genetic modification of source organism (enzyme from GM source microorganism)
N/A	B.1 Industrial use information (chemical only)	√	F.1 List of foods likely to contain the processing aid
N/A	B.2 Information on use in other countries (chemical only)	√	F.2 Anticipated residue levels in foods
N/A	B.3 Toxicokinetics and metabolism information (chemical only)	√	F.3 Information on likely level of consumption
N/A	B.4 Toxicity information (chemical only)	√	F.4 Percentage of food group to use processing aid
N/A	B.5 Safety assessments from international agencies (chemical only)	N/A	F.5 Information on residues in foods in other countries (if available)
√	C.1 Information on enzyme use on other countries (enzyme only)	N/A	F.6 Where consumption has changed, information on likely consumption
√	C.2 Toxicity information of enzyme (enzyme only)		